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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,059	12/29/2000	James R. Baker JR.	UM-04491	8985

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	PAPER NUMBER
1618	
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03/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/751,059	BAKER ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/16/08*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *186,189-194 and 199-206* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *186,189-194 and 199-206* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/4/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The examiner acknowledges receipt of request for extension of time, request for continued examination under 37 CFR 1/114, amendment and remarks filed 12/19/09. Claims 186, 200, and 202 are amended. Claim 197 is canceled. New claims 204-206 are added. Claims 186, 189-194 and 199-206 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/19/08 has been entered.

Response to Arguments

Previous rejections that are not reiterated herein have been withdrawn.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 186, 189-194 and 199-206 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

5. Claims 186, 200 and 202 recite the phrase "consisting essentially of" and the specification as originally filed does not envision composition that consists essentially of.

6. Claims 186, 189-194 and 199-206 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is written description.

7. Claims 186, 200 and 202 recite the phrase "consisting essentially of" and the specification as originally filed does not describe what applicant intends by a composition that consists essentially of. There is no description in the specification of compositions that meet that limitation.

8. The rejections may be overcome by removing the new matter and/or terms that are not originally described in the specification.

9. Claim 203 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 203 states that the cetylpyridinium chloride is at ... by volume of cetylpyridinium chloride. It is unclear how % amount of the cetylpyridinium chloride is compared to it self. Clarification is respectfully requested.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 186, 189-194 and 199-206 are rejected under 35 U.S.C. 103(a) as being unpatentable over Libin (US 5,855,872) in view of Stroud et al. (US 6,231,837).

Libin discloses method of treating diseased tissues that results from herpes simplex virus infection, by applying an oil in water emulsion that contains cetylpyridinium chloride, sterol alcohol, emulsifying agent and mineral oil (abstract; column 1, lines 42, 47-55; column 2, lines 26-64; column 3, line 25 to column 4 line 29) without specifically mentioning a human while disclosing topical application. Stroud teaches an oil in water emulsion (column 17, lines 51 and 52; column 18, lines 6 and 7; column 22, line 14) that is a self tanning composition (column 7, lines 28,29; column 11, line 26; column 12, lines 29 and 30) that contains glycerol (column 7, lines 39 and 40; column 15, lines 41 and 42), ethanol (column 11, line 41), antimicrobial or antifungal agents (column 18, lines 43-46), preservatives or chelating agent such as EDTA helps maintain the ionic strength of the composition(column 19, lines 26, and 54-59), antiviral agent for treating herpes simplex or herpes zoster or chickenpox (column 21, lines 7-9), emollients such as castor oil or soybean oil (column 21, lines 29-32) and surfactant such as polysorbate 20 (column 24, lines 30, 50 and 51), which is TWEEN 20; the oil in water emulsion of Stroud is formulated as cream, lotion or ointment (column 17, lines 31, 32). Stroud teaches that the self-tanning formulations are approved for use with humans (column 2, lines 61 and 65). Regarding the %amounts of ethanol, surfactant and % volume oil, the ordinary skilled artisan has within his or her technical grasp to use amounts of oil, surfactant and ethanol desired in the composition that would be effective to treat herpes simplex virus. Both compositions have utility in the treatment of herpes simplex virus via topical route so that a combination of the compositions of Stroud and Libin will yield a composition that would be effective in treating herpes simplex virus.

The application to human the combined composition that contains alcohol, surfactant, oil and the cetylpyridinium chloride meets claims 186-188, 197 and 200. The presence of the ETDA meets claims 189, 190 and 201. The presence of oil or soybean oil meets claims 191 and 192. Polysorbate 20, which is TWEEN 20 meets claims 193 and 194. Ethanol present in the formulation meets claims 186, 200 and 202. The topical application of the formulation in the form of ointment or lotion or cream meets claims 186, 199 and 200.

Both Libin and Stroud teach emulsion and emulsion is generic to microemulsion and nanoemulsion and therefore encompasses nanoemulsion and/or microemulsion. For new claims 204-206 that recite the particle size, it is noted that microemulsions and nanoemulsions have typical size ranges, for example, Jafari et al in the International Journal of Food Properties disclose nanoemulsions having particles in the size range of 150-700 nm (0.15-0.7 microns) (see the abstract) and Bouchemal et al in the International Journal of Pharmaceutics disclose the size of nanoemulsions at a range of 100-600 nm (0.1 to 0.6 micron). These typical sizes fall within the recited particle size for the claimed composition.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the composition of Stroud and Libin with the motivation that topically applying the composition to affected areas of a person in need thereof, and specifically to humans in view of Stroud, would treat the affected areas of herpes simplex. Treating the virus results from inactivating the virus and thus leads to decontaminating the affected area.

14. Claims 186, 191, 193, 194, 198-200, 204 and 205 are rejected under 35 U.S.C. 103(a) as unpatentable over Asculai et al. (US 4,020,183) in view of Keith et al. (US 4,350,707).

Asculai discloses inactivating herpes simplex virus in humans by applying to the infected area an effective amount of oil-in-water emulsion that contains surfactants such as polysorbate 20, which is TWEEN 20 (column 1, line 61; Table 1), halogen containing compound such as cetylpyridinium chloride or benzalkonium chloride (column 1, lines 16 and 17), mineral oil of petrolatum (column 2, lines 48 and 49), alcohols (line 41), the formulation is in the form of cream or lotion (column 2, line 46). Asculai describes method of inactivating the herpes simplex virus in humans by applying the composition to the affected areas (claims 1-6) and while Asculai does not use the term decontamination, inactivation naturally leads to decontamination so that Asculai inherently decontaminates surfaces of the human. Asculai uses surfactant in amounts of between 0.5% and 20%. The composition of Asculai does not contain ethanol as now recited in claims 186 and 200.

Asculai teaches emulsion and emulsion is generic to microemulsion and nanoemulsion and therefore encompasses nanoemulsion and/or microemulsion. For new claims 204 and 205 that recite the particle size, it is noted that microemulsions and nanoemulsions have typical size ranges, for example, Jafari et al in the International Journal of Food Properties disclose nanoemulsions having particles in the size range of 150-700 nm (0.15-0.7 microns) (see the abstract) and Bouchemal et al in the International Journal of Pharmaceutics disclose the size of nanoemulsions at a range of 100-600 nm (0.1 to 0.6 micron). These typical sizes fall within the recited particle size for the claimed composition.

But Keith uses ethanol containing composition to topically treat herpes simplex virus. Therefore, given the teachings of Asculai and Keith, one of ordinary skill in the art at the time the invention was made would have reasonable expectation of success to inactivate or treat

surfaces having the herpes simplex virus with the composition of Asculai to which has been ethanol. While the %ethanol used in Keith is higher than that recited, the mere fact a range is claimed indicates that the amount of the ethanol can be optimized to produce the composition effective to treat the surface of virus.

15. Claims 186, 189-194 and 199-206 are rejected under 35 U.S.C. 103(a) as being unpatentable over Libin (US 5,855,872) in view of Thomsen et al. (US 6,342,537, Thomsen 1) or Thomsen et al. (US 5,981,605, Thomsen II) and further in view of Mulder (US 5536502) and Asculai et al. (US 4,020,183).

16. Libin topically applies ointment (abstract, column 1, lines 21 and 49, column 5, line 13 and claim 4) comprising cetylpyridinium chloride, sterol alcohol, mineral oil and emulsifying agent as described in the rejections above for treating diseased tissues that results from herpes simplex virus infection (abstract; column 1, lines 42, 47-55; column 2, lines 26-64; column 3, line 25 to column 4 line 29) without specifically mentioning a human while disclosing topical application. Libin's composition also contains preservatives such as methyl paraben or propyl paraben (column 3, line 5). Libin uses sterol alcohol instead of ethanol. But ethanol is known to disinfect herpes simplex virus according to Thomsen 1 at column 23, lines 7-26) or Thomsen II at column 2, lines 40-42; column 4, lines 27-30; column 8, lines 17-23. However, it is known that EDTA and the parabens are preservatives (claim 12 of US 5536502) and one preservative can be used in place of the other without materially affecting the composition.

Libin teaches emulsion and emulsion is generic to microemulsion and nanoemulsion and therefore encompasses nanoemulsion and/or microemulsion. For new claims 204-206 that recite the particle size, it is noted that microemulsions and nanoemulsions have typical size ranges, for

example, Jafari et al in the International Journal of Food Properties disclose nanoemulsions having particles in the size range of 150-700 nm (0.15-0.7 microns) (see the abstract) and Bouchemal et al in the International Journal of Pharmaceutics disclose the size of nanoemulsions at a range of 100-600 nm (0.1 to 0.6 micron). These typical sizes fall within the recited particle size for the claimed composition.

17. Therefore, taking the teachings of the prior art, one having ordinary skill in the art at the tine the invention was made would have reasonable expectation of success that using ethanol in place of the sterol alcohol, and using EDTA in place of the parabens in the composition of Libin would effectively treat diseased tissues that results from herpes simplex virus infection. Furthermore, the composition of Libin can be topically applied to human since it is known in the art that cetylpyridinium containing emulsion is known to inactivate herpes simplex virus in humans by applying to the infected area as evidenced by Asculai at column 1, line 61 and Table 1.

Response to Arguments

18. Applicant's arguments filed 12/19/08 have been fully considered but they are not persuasive. It is noted that the applicant has argued the references together and the response given below is also applicable to the rejections: i) Claims 186, 189-194 and 199-206 rejected under 35 U.S.C. 103(a) as being unpatentable over Libin (US 5,855,872) in view of Stroud et al. (US 6,231,837); ii) Asculai et al. (US 4,020,183) in view of Keith et al. (US 4,350,707); and iii) Libin (US 5,855,872) in view of Thomsen et al. (US 6,342,537, Thomsen 1) or Thomsen et al.

(US 5,981,605, Thomsen II) and further in view of Mulder (US 5536502) and Asculai et al. (US 4,020,183)

19. Applicant argues that a) the cited references, "individually or in combination do not teach or suggest method of topically treating a human having a *Herpes Simplex I virus* infection" by exposing the surface of a skin or mucosal cells and tissue of a human to nanoemulsion composition or dilution thereof (claim 186). Applicant has also stated that the use of the phrase consisting essentially of in the claims excluded the compositions of the cited references. The examiner disagrees. Libin in view of Stroud topically applies ointment (Libin at abstract, column 1, lines 21 and 49, column 5, line 13 and claim 4) comprising cetylpyridinium chloride, alcohol, mineral oil and emulsifying agent as described in the rejections; Stroud teaches that compositions such as that described for Libin is approved for use with humans . If the difference in applicant's view is the respective amounts of ethanol, surfactant and the halogen containing compound, halogen containing compound, it would be well within the technical grasp of the ordinary artisan to use amounts of ethanol, surfactant and halogen containing compound that would provide an emulsion that when topically applied to the human skin would treat diseased tissues resulting form herpes simplex virus infection. If the difference is that the prior art teaches emulsion and the claims recited nanoemulsion, it is noted that nanoemulsion is a type of emulsion (see definition of emulsion and nanoemulsion from Answers.com, http://www.answers.com/topic/emulsion). Topically applying nanoemulsion composition comprising disperse or oil phase, continuous or aqueous phase, 3-15% ethanol, 3-15% surfactant and 0.5-2% or 1-10% of cetylpyridinium chloride is not inventive over the prior art that topically

applies an emulsion comprising disperse or oil phase, continuous or aqueous phase, ethanol, surfactant and cetylpyridinium chloride.

20. Furthermore, consisting essentially of language limits the scope of the claim to the specified materials and those that do not materially affect the basic and novel characteristics of the claimed invention. In the present case, the novel characteristic of the claimed invention is treating *Herpes Simplex I virus* infection. In the same way, the prior art, Libin in view of Stroud teaches treating *Herpes Simplex I virus* infection. Therefore, the presence of what applicant terms to be excluded does not materially affect the novel and basic characteristic of the claimed invention. Further also, according to MPEP 2111.03 [R-3], "A consisting essentially of' claim occupies a middle ground between closed claims that are written in a consisting of' format and fully open claims that are drafted in a comprising' format." PPG Industries v. Guardian Industries, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). See also Atlas Powder v. E.I. duPont de Nemours & Co., 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); In re Janakirama-Rao, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); Water Technologies Corp. vs. Calco, Ltd., 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355.

21. Applicant argues that there is no motivation to combine the references. The examiner disagrees. Libin and Stroud, each teach compositions that are topically applied to treat *Herpes*

Simplex I virus infection. Thus, there is reasonable expectation that the combination of the two compositions that are separately taught in the art to treat *Herpes Simplex I virus* infection would be effective in also treating the *Herpes Simplex I virus* infection. In the same way, Asculai describes inactivating *Herpes Simplex I virus* while Keith describes using ethanol containing composition to treat *Herpes Simplex I virus* infection; thus because the goal of Keith and Asculai intersect or meet, one having ordinary skill in the art at the time the invention was made would reasonably expect that the addition of ethanol to composition of Asculai would produce the anticipated effect, that is, to treat *Herpes Simplex I virus* infection. There in lies the motivation. It is also however noted that the court in the KSR case was clear that the TSM test is not the only test.

22. Applicant's arguments against Libin in view of Stroud and Asculai in view of Keith is the same as that against Libin (US 5,855,872) in view of Thomsen et al. (US 6,342,537, Thomsen 1) or Thomsen et al. (US 5,981,605, Thomsen II) and further in view of Mulder (US 5536502) and Asculai et al. (US 4,020,183). Therefore, the response provided above also applies here.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Blessing M. Fubara/
Examiner, Art Unit 1618